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Washington, D.C. 20231

DEC 24 1996

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. Re. 34,353, was filed on February 20, 1996, under 35 U.S.C. § 156. The application was found to be deficient and a notice of deficiencies was mailed October 31, 1996, a copy of which is attached. An amended application for patent term extension was filed on December 2, 1996 and is also attached. U.S. Patent No. Re. 34,353 is a reissue of U.S. Patent No. 4,657,021 and has an original expiration date of April 24, 2005.

The assistance of your Office is requested in confirming that the product identified in the application, SENSOR PAD®, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved for commercial marketing or use under § 515 of the Federal Food, Drug and Cosmetic Act (FFDCA). Since a determination has not been made whether the patent in question claims a product which has been subject to the FFDCA, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would not be eligible for extension of the patent term under 35 U.S.C. § 156 if the regulatory review period under section 515 of the FFDCA ended with approval of the product, SENSOR PAD®, more than 60 days before the application for patent term extension was filed, February 20, 1996 or if the approval was not under section 515 of the FFDCA. On page 4 of the amended application, applicant states that the product was "cleared for sale ... on December 22, 1995." However this date does not appear to be the date an application submitted under section 515 of the FFDCA was approved and instead appears to be the date the SENSOR PAD® received permission for commercial marketing or use following the fourth 510(k) application, as stated on page 5 of the amended application. Regulatory review under section 510(k) of the FFDCA is not considered part of the regulatory review period under 35 U.S.C. § 156(g)(3)(B) and therefore regulatory review under section 510(k) is not a "regulatory review period" which gives rise to eligibility for patent term extension under 35 U.S.C. § 156(a). In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492 (Pat. Policy and Programs Admin. 1990). Receipt of permission to market is not "approval" of the product under the FFDCA. See Applications for Patent Term Extension for U.S. Patent Nos.

4,621,638 (Dekantel Microflex Ophthalmic Suture) and 4,776,838 (Orbis-Sigma Valve).

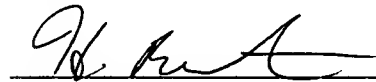
Furthermore, 35 U.S.C. § 156(a)(4) requires that the product be subject to a regulatory review period before its commercial marketing or use. This is understood to mean that the regulatory review period must have ended before the first commercial marketing or use of the product. On page 5 of the application for patent term extension, filed February 20, 1996, applicant stated that the marketing of the product, SENSOR PAD®, began on March 21, 1988 and continued in the United States until April 18, 1989. Since the regulatory review period had not ended (the regulatory review period ended December 22, 1995) when commercial marketing began, it would appear that U.S. Patent No. Re. 34,353 is not eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review of SENSOR PAD®.

Moreover, the patent does not appear to claim the approved product. The Polyurethane film of SENSOR PAD® is said to have a modulus at 300 percent elongation of about 1,650 psi which is greater than the "less than about 1,500 psi" that is claimed in the patent.

Telephone inquiries regarding this communication should be directed to the Karin Tyson at (703) 306-3159.



Karin Tyson
Legal Advisor



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Enclosures: Application for Patent Term Extension, filed February 20, 1996
Notice of Deficiencies, mailed October 31, 1996
Amended Application for Patent Term Extension, filed December 2, 1996

cc: Philip L. Bateman
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